REMARKS

The applicants have studied the Office Action dated March 15, 2006, and have made amendments to the application. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 36-59 are pending and no amendments to the claims have been made. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Applicants wish to thank the Examiner for acknowledging that claims 2-35 were originally canceled in the divisional application transmittal letter dated January 4, 2002. In accordance with the Examiner's instructions, claims 38-61 (which were added in the preliminary amendment filed on April 29, 2002) have been renumbered 36-59 since the original application only had claims 1-25.

The Examiner has noted that a reference to prior Application No. 09/346,835, now U.S. Patent No. 6,368,141, and prior Application No. 08/871,831, now U.S. Patent No. 5,954,643, should be included as the first sentence of the specification or in an application data sheet. In response to this notation, applicants respectfully request the Examiner to draw his attention to paragraphs 5 and 7b of the divisional application transmittal letter dated January 4, 2002. In paragraph 5, applicants marked an X requesting the Patent and Trademark Office to "[a]mend the specification by inserting after the title: - - This is a divisional application of U.S. Patent Application Serial No. 09/346,835 filed July 2, 1999, which is a divisional application of U.S. Patent Application Serial No. 08/871,831 filed June 9, 1997, now U.S. Patent No. 5,954,643." Additionally, in paragraph 7b of the transmittal letter, applicants claim priority to both applications. Domestic priority data regarding these prior applications was confirmed on the original filing receipt dated February 8, 2002 and the updated filing receipt dated May 17, 2002. Accordingly, applicants respectfully request that priority to these prior applications be accepted. For thoroughness, applicants have included in this response an amended specification which adds the patent number information to Application No. 09/346,835.

In paragraph 4 of the Office Action, the Examiner states that the title of the invention is not descriptive. Once again, applicants request the Examiner to draw his attention to page 1 of the divisional application transmittal letter dated January 4, 2002. In the transmittal letter, the title of the invention is listed as: "Insertion Set for a Transcutaneous Sensor with Cable Connector Lock Mechanism." Applicants feel that this title is indeed descriptive and corresponds with the claimed subject matter. Accordingly, applicants respectfully request that the title listed in the divisional application transmittal letter be accepted.

Claims 36-39, 41-44, 46-51, 53-56 and 58-59 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,840,613 to Balbierz. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an improved insertion set for transcutaneous placement of a sensor in a patient and/or transcutaneous delivery of a fluid to a patient. In particular embodiments, the insertion set includes a mounting base adapted for mounting onto the patient's skin and a cannula coupled to the mounting base and having a distal end protruding from the mounting base. The cannula is adapted for transcutaneous delivery of fluid, such as medication, to the patient. The mounting base further includes at least one resilient latch arm projecting from the mounting base, which is adapted for releasable engagement with at least one corresponding recess on a connector for infusion tubing used in conjunction with the insertion set.

In general, embodiments of the present invention describe a device and method that allows two pieces of a medical device to be disconnected and reconnected on demand by the patient in a relatively easy fashion. The first piece, an insertion set, which includes the mounting base and the cannula, is placed on the patient's skin. The infusion tubing is a separate piece altogether that is connected, at one end, to an infusion device. In particular embodiments, fluid from the infusion device should run through the infusion tubing and then enter the body of the patient through the insertion set. Accordingly, an aspect of the invention is to create fluid communication between the infusion device (via infusion tubing) and the insertion set mounted on the patient's skin. However, to have a permanent connection between the infusion device (via

infusion tubing) and the insertion set mounted on the patient's skin would mean that the patient would always be physically connected to the infusion device. In these instances if a patient needed to, for example, take a shower, they would have to physically remove the insertion set from their skin. After the shower, they would have to reinsert a new insertion set to connect back up to the infusion device, which would require another piercing of the skin to transcutaneously place the cannula.

To avoid such situations, the claimed subject matter recites a device and method where a patient can easily disconnect and reconnect their insertion set to the infusion device (via infusion tubing). In particular embodiments, a connector is attached to the opposite end of the infusion tubing (the end not connected to the infusion device). The connector attached to the infusion tubing allows for releasable engagement to the insertion set's mounting base. In particular embodiments, the connector attached to the infusion tubing contains two recesses and the mounting base of the insertion set includes two resilient latch arms that extend from the end of the mounting base. The resilient latch arms project from the mounting base and facilitate releasable engagement of the mounting base with the connector.

In order to disconnect or reconnect the mounting base and the connector, the patient is required to disengage or re-engage only the latch arms on the mounting base, and simply move the connector away or toward the mounting base. It is easier for the patient to hold the mounting base and maneuver the latch arms on the mounting base because the mounting base is stabilized on the patient's skin. Such a latch mechanism for releasable engagement of the mounting base with the connector is especially useful for patients with dexterity problems.

The Balbierz reference is drastically different from the present invention. The Balbierz reference is directed to a protective sheath for a catheter assembly and a locking mechanism for ensuring that the sheath be adequately positioned and locked in place to protect a cannula from kinking and accidental withdrawal. However, the Balbierz reference does not specifically disclose "[a]n insertion set for use with infusion tubing having a connector with at least one recess on the connector adapted for coupling the infusion tubing to the insertion set . . ." as described in the claims.

In general, the Balbierz reference, as shown in FIG. 1, sets forth a protective sheath for a catheter assembly. In use, the distal end 14 of a cannula 12 slidably fits in a guide channel 20 of an inserter 22. The proximal end 16 of the cannula 12 is attached to a hub structure 28. A sheath 36 surrounds the cannula 12 and is also connected to the hub structure 28. The sheath 36 includes a longitudinal slit 41. As the cannula 12 passes through the guide channel 20 of the inserter 22, sheath stripping means 42 strip the sheath 36 and expose the cannula allowing it to be fed through the guide channel 20. Once the desired length of cannula 12 has been fed into the patient, a second lock member 62 (slidably positioned about the sheath 36) is slid over the sheath 36 towards the inserter 22, where it ultimately interlocks with a first lock member 52 (carried by the inserter 22). The second lock member 62 is designed so that when it is locked into position with the first lock member 52, the sheath 36 is restricted from further motion which provides protection from accidental withdrawal of the cannula 12 when personnel are manipulating the hub structure 28 during routine usage of the device. (Balbierz, col. 8, line 53 – col. 10, line 40).

The Examiner mischaracterizes many of the features in the Balbierz reference is his 102(b) rejection described in paragraph 7 of the Office Action. The Examiner explains that item 36 in Balbierz is the infusion tubing of the claimed subject matter. However, the reference clearly explains that item 36 is a sheath used to protect the cannula 12—"a sheath 36 is provided having a sheath distal end . . . and a sheath proximal end . . . located about the cannula 12 between the inserter 22 and the hub structure 28" (col. 9, lines 5-17). The sheath 36 in the Balbierz reference is never described as infusion tubing "wherein the infusion tubing is adapted for delivering fluid through the connector to the insertion set" as stated in claim 36.

Furthermore, the sheath 36 has a longitudinal slit 41 which exists to allow the sheath 36 to be stripped away upon passing through the stripping means 42. Since the sheath 36 is stripped away in the Balbierz reference, there is no possible way fluid can pass through the sheath 36 in the same way that fluid passes through the infusion tubing of the claimed subject matter. If fluid were passed through the sheath 36, fluid would end up everywhere at the area of first lock member 52 where the sheath 36 is stripped away from the cannula 12.

Next, the Examiner explains that item 62 in the Balbierz reference is the connector disclosed in the claimed subject matter. The connector of the claimed subject matter is shown in figures 12 and 13 of the specification. As shown in these figures, the connector 20 is physically attached to the infusion tubing and/or connector cable 22. However, in the Balbierz reference the second lock member 62 is "slidably positioned about the sheath 36" (col. 9, lines 61-62) and "is free of connection with the hub structure 28" (col. 9, line 67-68). Clearly, the second lock member 62 of the Balbierz reference is not the same as the connector disclosed in the claimed subject matter because the second lock member of Balbierz slides over the sheath and is not physically connected to the hub structure 28.

Independent claim 36 specifically recites "an insertion set for use with infusion tubing having a connector." The connector disclosed in the claims is not "slidably positioned about a sheath" as described in Balbierz. Rather, the connector recited in the claimed subject matter is attached in a fixed position to one end of the infusion tubing and/or connector cables. The connector is further "adapted for coupling the infusion tubing with the insertion set." Most importantly, however, the connector of the claimed subject matter does not slide about a cannula which is covered by a sheath as recited in Balbierz; it is attached in a fixed position to the infusion tubing.

The Balbierz reference describes a device quite different from the claimed subject matter. The nature of the reference is to provide a protective sheath for a catheter assembly and not to provide "[a]n insertion set for use with infusion tubing having a connector . . . adapted for coupling the infusion tubing to the insertion set . . ." as recited in the claims. Since the Balbierz reference does not disclose all elements of the claimed subject matter, it cannot anticipate the claims.

The dependent claims are further distinguished by virtue of depending on independent claims 36, 43, 48, 55, and 58, and reciting additional features not provided for in the Balbierz reference.

Therefore, it is respectfully submitted that the rejection of claims 36-39, 41-44, 46-51, 53-56 and 58-59 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 40, 45, 52, and 57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Balbierz (U.S. Patent No. 4,840,613) in view of Lord et al. (U.S. Patent No. 5,390,671). This rejection is respectfully traversed.

The dependent claims 40, 45, 52 and 70 depend from the independent claims which were patentably distinguished from the Balbierz reference as discussed above. Accordingly, claims 40, 45, 52 and 70 are also distinguished over the Balbierz reference.

Therefore, it is respectfully submitted that the rejection of claim 10 under 35 U.S.C. § 103(a) should be withdrawn.

The Examiner also rejected claims 36-59 on the ground of nonstatutory obviousness-type double patenting over claims 7-11 and 20-35 of U.S. Patent No. 5,954,643. A terminal disclaimer is being filed concurrently with this amendment. Therefore, it is respectfully submitted that the double patenting rejection be withdrawn.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5003 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

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